DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18, 2014

Precision Spine
% Mr. Kenneth C. Maxwell II
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K142378
Trade/Device Name: Interspinous Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: November 14, 2014
Received: November 20, 2014

Dear Mr. Maxwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142378

Device Name
Interspinous Plate System

Indications for Use *(Describe)*

The Interspinous Plate System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1) of skeletally mature patients. It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (i.e. fracture or dislocation), spondylolisthesis, and/or tumor. It is not intended for stand-alone use.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) SUMMARY

Submitter's Name:	Precision Spine
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	973-455-7150
Contact Person:	Kenneth C Maxwell II Empirical Testing Corp. 904.392.7576
Date Summary was Prepared:	11 December 2014
Trade or Proprietary Name:	Precision Spine Interspinous Plate System
Common or Usual Name:	Spinous Process Plate
Classification:	Class II per 21 CFR §888.3050 Spinal interlaminal fixation orthosis
Product Code:	PEK
Classification Panel:	87 Orthopedics

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Precision Spine Interspinous Plate System consists of an ISP female plate and an ISP male plate for posterior fixation of the spine in order to achieve fusion. The ISP female plate and an ISP male plate are available in multiple sizes to accommodate various patient anatomies. The ISP female plate and an ISP male plate feature teeth to interface with the bone of the spinous processes. The ISP male plate is passed through the insert such that, in their final position, the ISP female plate and an ISP male plate surround the spinous processes on both sides, and fixation is achieved via compression of the two components onto the spinous processes.

INDICATIONS FOR USE

The Interspinous Plate System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1) of skeletally mature patients. It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (i.e. fracture or dislocation), spondylolisthesis, and/or tumor. It is not intended for stand-alone use.

TECHNOLOGICAL CHARACTERISTICS

The Precision Spine Interspinous Plate System is manufactured from medical grade Titanium (Ti 6Al-4V) per ASTM F136. The implants are provided non-sterile with instructions for sterilization. The interspinous plates are designed in total heights of 35-55mm.

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sterilization

Table 5-1: Primary Predicate Device

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K133363	InterBRIDGE Interspinous Posterior Fixation System	LDR Spine USA, Inc.

Table 5-2: Additional Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K073278, K131238	Affix Spinous Process Plate System	NuVasive®
K123093	StabiLink™ MIS Spinal Fixation System	Southern Spine
K100354	PrimaLOK™ Interspinous Fusion System	OsteoMed
K122509	Spinous Process Fixation Plate	VertiFlex®

PERFORMANCE DATA

The Precision Spine Interspinous Plate System has been tested in the following test modes:

- Static axial compression per ASTM F1717-13
- Static torsion per ASTM F1717-13
- Dynamic axial compression per ASTM F1717-13
- Static axial pull-out
- Static plate dissociation

The results of this non-clinical testing show that the strength of the Interspinous Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Interspinous Plate System is substantially equivalent to the predicate device.